MAY - 1 2000

K001085

510 (k) Summary

SUBMITTER:		**Nonin Medical, Inc.**
	Address:	**Nonin Medical, Inc.** **2605 Fernbrook Lane North** **Plymouth, MN 55447-4755**
	Telephone:	**612.553.9968**
CONTACT PERSON:		**Richard P. Bennett, Director of Regulatory Affairs**
DATE PREPARED:		**March 14, 2000**
TRADE NAME:		**Nonin® Onyx®, Model 9500 Finger Clip Pulse Oximeter**
COMMON NAME:		**Pulse Oximeter**

SUBSTANTIALLY EQUIVALENT TO:

The Nonin Onyx, Model 9500 Finger Clip Pulse Oximeter

DESCRIPTION OF THE DEVICE:

The Model 9500 Pulse Oximeter determines arterial hemoglobin saturation (%SpO2) by measuring absorption of red and infrared (IR) light passed through the tissue. The light emitting diodes (LEDs) are contained within the sensor along with the photo detector which is on the opposite side of the probe from the LEDs. The Spo2 and heart rate are displayed on LED digital displays contained within the finger clip sensor. All associated electronics and the microprocessor are within the sensor, which is activated by inserting a patient's finger. This allows power to be applied to all the internal circuitry upon activation. The device is very small (1.3" x 1.3" h x 2.2") and very light (2 oz.). The device is intended for spot checking and short-term monitoring of adult and pediatric patients.

INDICATIONS FOR USE:

The Nonin® Finger Clip (miniaturized) Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate.

510 (k) Summary

SUMMARY OF TESTING:

The Model 9500 Finger Clip Pulse Oximeter has followed (where applicable, the Reviewer Guidance for Premarket Notification Submission of November 1993, from the Anesthesiology and Respiratory Branch, Division of Cardiovascular, Respiratory and Neurological Devices. In addition, Nonin has conducted a Hazard Analysis and Risk Assessment, and developed extensive software/hardware procedures to confirm the performance of the product to the design requirements. Bench and clinical testing has been done to verify the performance of the device in a clinical environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2000

Mr. Richard P. Bennett
Director of Regulatory Affairs
Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Re: K001085
Model 9500 Finger Clip Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: March 31, 2000
Received: April 4, 2000

Dear Mr. Bennett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Melvin Lewis for,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

K001085

Device Name:

Onyx, Model 9500, The Nonin® Finger Clip (miniaturized) Pulse Oximeter_

Indications for Use:

The Nonin® Finger Clip (miniaturized) Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), and pulse rate.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____